AP-1744

Docket No.: CI-0012

PATENT

#7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of :

Shirley MIEKKA, Martin J. MACPHEE, William N. DROHAN, David M. MANN and Wilson BURGESS :

: Group Art Unit: 1744

Serial No.: 09/960,703 :

: Examiner: To be assigned

Filed: September 24, 2001 :

For: METHODS OF STERILIZING PREPARATIONS OF NON-AQUEOUS SOLVENTS

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).

— 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).

_ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

_ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

_ c. Attached is our check no. _____ in the amount of $180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

_ 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ___ in the amount of $180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).

_ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

_ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

_X_ 4. The relevancy of the non-English language references can be determined from the attached abstracts.

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP

Mark L. Fleshner
Registration No. 34,596
Donald R. McPhail
Registration No. 35,811

Correspondence Address:
P.O. Box 221200
Chantilly, VA 20153-1200
Telephone: (703) 502-9440
Date: **August 26, 2002**
MLF:DRM/dbp

LIST OF PRIOR ART CITED BY APPLICANT
SUBSTITUTION FOR
(PTO-1449)

ATTY. DOCKET NO.	APPLN. SERIAL NO.
CI-0012	**09/960,703**
APPLICANT: **Shirley MIEKKA et al.**	
FILING DATE: **September 24, 2001**	GROUP: **1744**

U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A1	4,336,247	06/1982	Eriksen			
	A2	4,931,361	06/1990	Baldeschwieler et al.			
	A3	5,012,503	04/1991	Nambu et al.			
	A4	5,044,091	09/1991	Ueda et al.			
	A5	5,856,172	01/1999	Greenwood et al.			
	A6	6,010,719	01/2000	Remon et al.			
	A7	6,060,233	05/2000	Wiggins			
	A8	6,258,821	07/2001	Stogniew et al.			
	A9						
	A10						
	A11						

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B1						

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	FILING DATE
	C1						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D1							
	D2							
	D3							
	D4							
	D5							

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E1	Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, J. Biomedical Materials Research, 20:469-479 (1986) (John Wiley & Sons, Inc.)
	E2	Borisova, E.A. et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radation and Dexamethasone, pp.519-521 (1990)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

LIST OF PRIOR ART CITED BY APPLICANT
SUBSTITUTION FOR
(PTO-1449)

ATTY. DOCKET NO.	APPLN. SERIAL NO.
CI-0012	**09/960,703**
APPLICANT: **Shirley MIEKKA et al.**	
FILING DATE: **September 24, 2001**	GROUP: **1744**

OTHER ART

EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E3	Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione *S*-Transferase, The Journal of Biological Chemistry, 261:16963-16968 (1986)
	E4	Chanderkar, L.P. et al., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, Radiation Research, 65:283-291 (1976) (Academic Press, Inc.)
	E5	Chanderkar, L.P. et al., Radiation-Induced Changes In Purified Prothrombin and Thrombin, Biochimica et Biophysica Acta, 706:1-8 (1982) (Elsevier Biomedical Press)
	E6	Chin, S. et al., Virucidal Treatment of Blood Protein Products With UVC Radiation, Photochemistry and Photobiology, 65:432-435 (1997) (American Society for Photobiology)
	E7	Dyskin, E.A. et al., Hemomicrocirculatory Bed in the Wall of Hollow Organs of the Dog Gastrointestinal Tract at Portal Hypertension, Arkh Anat Gistol Embiol, 93:58-68 (1987)
	E8	Hsiue, G. et al., Absorbable Sandwich-Like Membrane for Retinal-Sheet Transplantation, pp.20-25 (2002) (Wiley Periodicals, Inc)
	E9	Jensen, J. et al., Membrane-bound Na, K-ATPase: Target Size and Radiation Inactivation Size of Some of Its Enaymatic Reactions, J. Biological Chemistry, 263:18063-18070 (1988) (Am. Soc. for Biochem. and Mol. Biol.)
	E10	Kamat, H.N. et al., Correlation of Structrual Alterations in Bovine Fibrinogen with Loss of Clotting Properties After Gamma Irradiation, Radiation Research, 49:381-389 (1972) (Academic Press, Inc.)
	E11	Kempner, E.S. et al., Effect of Environmental Conditions on Radiation Target Size Analyses, Analytical Biochemistry, 216:451-455 (1994)
	E12	Kempner, E.S. et al., Radiation-Damaged Tyrosinase Molecules are Inactive, Biophysical Journal, 55:159-162 (1989) (Biophysical Society)
	E13	Kuijpers, A.J. et al., *In vivo* Compatibility and Degradation of Crosslinked Gelatin Gels Incorporated in Knitted Dacron, pp.137-144 (2000) (John Wiley & Sons, Inc.)
	E14	Le Maire, M. et al., Effects of Ionizing Radiations on Proteins, Journal of Biochem., 267:431-439 (1990)
	E15	License Amendment and Procedures for Gamma Irradiation of Blood Products, Dept. of Health & Human Services, Food and Drug Administration, pp. 1-18 (June 22, 1993)
	E16	Ma, J.T. et al., Functional Size Analysis of F-ATPase from *Escherichia coli* by Radiation Inactivation, The Journal of Biological Chemistry, 268:10802-10807 (1993) (The Am. Soc. for Biochem. and Mol. Bio., Inc.)
	E17	Marx, G. Protecting Fibrinogen with Rutin During UVC Irradiation for Viral Inactivation, Photochemistry and Photobiology, 63:541-546 (1996) (American Society for Photobiology)
	E18	The Merck Index, Eleventh Edition, Glucose, pp. 699-700 (1989) (Merck & Co., Inc.
	E19	Nagrani, S. et al., The Radiation-Induced Inactivation of External Yeast Invertase in Dilute Aqueous Solution, Int. J. Radiat. Biol., 55:191-200 (1989) (Taylor & Francis Ltd.)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

LIST OF PRIOR ART CITED BY APPLICANT
SUBSTITUTION FOR
(PTO-1449)

ATTY. DOCKET NO.	APPLN. SERIAL NO.
CI-0012	09/960,703
APPLICANT: Shirl y MIEKKA et al.	
FILING DATE: September 24, 2001	GROUP: 1744

OTHER ART

EXAMINER'S INITIALS	CITE NO	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E20	Nielsen, M. et al., The Apparent Target Size of Rat Brain Benzodiazepine Receptor, Acetylcholinesterase, and Pyruvate Kinase Is Highly Influenced by Experimental Conditions, The Journal of Biological Chemistry, 263:11900-11906 (1988) (The American Society for Biochemistry and Molecular Biology, Inc.)
	E21	Potier, M. et al., Radiation Inactivation of Proteins: Temperature-Dependent Inter-Protomeric Energy Transfer in Ox Liver Catalase, Biochem. J., 298:571-574 (1994)
	E22	Sakai, T. et al., Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation, Chem. Pharm. Bull., 26:1130-1134 (1978)
	E23	Salim-Hanna, M. et al., Free Radical Scavenging Activity Of Carnosine, Free Rad. Res. Comms., 14:263-270 (1991) (Harwood Academic Publishers GmbH)
	E24	Shcheglova, S.G. et al., The Effect of the Power of Gamma-Radiation on the Radiation dose in the Sterilization of Drugs, Khim Farm ZH, 18:730-732 (1984) Derwent (Abstract) No. 111469
	E25	Song, K.B. et al., Effect of Gamma-irradiation on the Physicochemical Properties of Blood Plasma Proteins, 2002 Annual Meeting and Food Expo-Anaheim, California, Session 30C-1, Food and Chemistry: Proteins, (June 2002) (Abstract)
	E26	Suomela, H., Inactivation of Viruses in Blood and Plasma Products, Transfusion Medicine Reviews, 7:42-57 (1993) (W.B. Saunders Company)
	E27	(Abstract of EP0919198A2 and EP0919198A3 (Delphion-DERABS Abstract # G1999-304614))
	E28	Website: www.wslfweb.org/docs/dstp2000.dtopdf/19-MD.pdf (Defense Science and Technology Plans, (February 2000) p. 176, Section II, MD.03, U.S. Department of Defense Deputy Under Secretary of Defense (Science and Technology))
	E29	Website: www.usacc.org/ataccc/ppt.html, (Advanced Technology Applications for Combat Casualty Care, 2001 Presentations, US Army Medical Research and Material Command Combat Casualty Care Research Program (2001))
	E30	Website: www.usacc.org/RevisedStepB.html, Bakaltcheva, I. et al., (FY01 Request for Proposals-Intramural-Revised 2, Combat Casualty Care Research Program, (2002))
	E31	Website: www.benvue.com/history/history_content.html, (2002)
	E32	Website: www.phase-technologies.com/html/vol.2no1.html , Jennings, T.A., (Glossary of Terms for Lyophilization) (1999)
	E33	Website: www.phase-technologies.com/html/vol.1no9.html , Jennings, T.A., (Overview of the Lyophilization Process) (1998)
	E34	Website: www.phase-technologies.com/html/vol.1no2.html , Jennings, T.A., (Role of Product Temperature in the Lyophilization Process) (1998)
	E35	Website: www.phase-technologies.com/html/vol.2no2.html , Jennings, T.A., (What I Wish I Knew About Lyophilization) (1999)
	E36	Website: www.phase-technologies.com/html/vol.1no7.html , Jennings, T.A., (Which Shelf Temperature During Lyophilization?) (1998)
	E37	Website: www.phase-technologies.com/html/vol.1no10.html , Jennings, T.A., (Yes, You have no Eutectic) (1998)
	E38	

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.